

**REMARKS**

Claims 1, 2, 5-9, 11 and 16-19 are pending. No new matter has been added by way of the above amendments. For example, the definition of Q' has been amended in claims 6 and 19. This definition is supported by the present specification at page 38, lines 14-16, page 39, lines 19-21, page 40, lines 1-2 from the bottom of formula (II'') and page 41, lines 9-11. Accordingly, no new matter has been added.

In view of the following remarks Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

**Issues Under 35 U.S.C. §112, first paragraph**

The Examiner has rejected claims 6 and 19 under 35 U.S.C. §112, first paragraph asserting that the definition of Q' in these claims is not supported by the specification. Applicants respectfully traverse this rejection and submit that claims 6 and 19 have been amended such that the definitions of Q' are consistent with the description of the present specification. Accordingly, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

**Objection to the Claims**

The Examiner has objected to claim 7 asserting that it is dependent upon a rejected base claim. Applicants traverse this rejection. Claim 7 depends upon claim 6, which was rejected by the Examiner. However, the rejection of claim 6 has been overcome. Accordingly, the objection to claim 7 is moot. Reconsideration and withdrawal thereof are respectfully requested.

**Allowable Subject Matter**

At page 3 of the outstanding Office Action the Examiner asserts that claims 1, 2, 5, 8, 9, 11 and 16-18 are allowable. In view of the fact that the rejections of claims 6 and 19 and the objection to claim 7 have been overcome, all currently pending claims are now in condition for allowance. However, the Examiner asserts that the present subject matter overlaps with subject matter of United States Patent Numbers 6,403,595 B1 and 6,359,134 B1. Applicants respectfully disagree with the Examiner.

**No Interfering Subject Matter Exists**

The Examiner states that a potential interference seems prominent because allowable claims appear to overlap with the subject matter in two U.S. patents (6,403,595 B1 and 6,359,134 B1). Applicants submit that there is no interfering subject matter

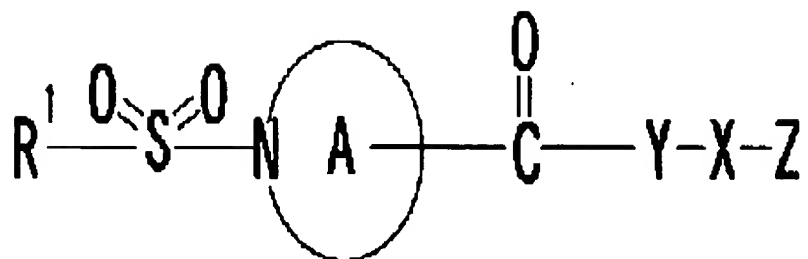
between the present claims and the claims of the U.S Patent No. 6,359,134.

First, the claims of U.S. Patent No. 6,359,134 B1 (hereinafter referred to as the '134 patent) do not overlap with the claims of the present application no. 09/582,442 (hereinafter referred to as the present application) since the patentee of the '134 patent clearly excludes the compounds of the present application in the '134 claims. In addition, it is respectfully submitted that the claims of the present application do not define the "same patentable invention" as the claims of the '134 patent within the meaning of 37 C.F.R. 1.601(j) and (n). Second, U.S. Patent No. 6,403,595 B1 (hereinafter referred to as the '595 patent) is distinct from the '134 patent.

**No overlap exists between the present claims and the claims of U.S. Patent No. 6,359,134 B1**

Claim 1 of the '134 patent excludes the formula (I') of the present application.

In detail, the claims of the '134 patent were intentionally limited at the filing date of the International Application corresponding to WO98/54164. The formula of a compound of the '134 patent claimed in claim 1 is as follows:

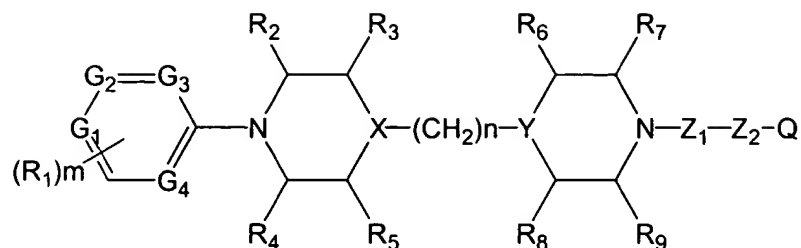


The definitions of Y, X and Z are as follows.

"Y is an optionally substituted divalent cyclic hydrocarbon group or an optionally substituted divalent heterocyclic group; X is a direct bond or an optionally substituted alkylene chain; Z is (1) an amino group substituted with an optionally substituted hydrocarbon group, (2) an optionally substituted imido group or (3) an optionally substituted nitrogen-containing heterocyclic group; provided that when X is a direct bond and Z is an optionally substituted 6-membered nitrogen-containing aromatic heterocyclic group, Y is an optionally substituted divalent cyclic hydrocarbon group or an optionally substituted divalent unsaturated heterocyclic group; or a salt thereof.

Claim 1 of the '134 patent does not include compounds having Y as a divalent saturated heterocyclic group when X is a direct bond and Z is an optionally substituted 6-membered nitrogen-containing aromatic heterocyclic group.

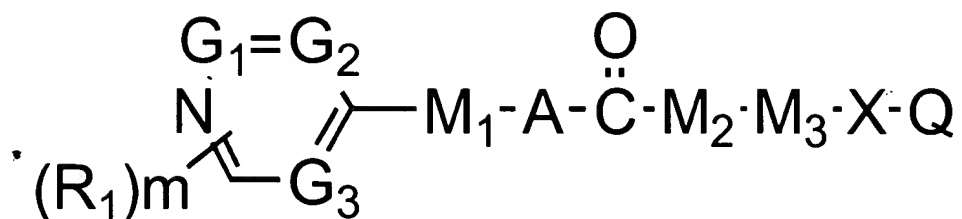
On the contrary the now allowable formula (I') of claim 1 of the present application is as follows:



In short the ring including X of the present application which is corresponds to Y of the '134 patent is a divalent saturated heterocyclic group, which the claims of the '134 patent do not include.

The '134 patentee intentionally excludes the compounds having Y is a divalent saturated heterocyclic group in the '134 patent from the filing date. The reasons for the exclusion is to avoid possible overlapping to prior art. WO 96/10022 (The assignee being Zeneca) is referred as the prior art in the '134 patent. It is noted that WO 96/10022 is also referred in the present application and was submitted with an Information Disclosure Statement. WO 96/10022 describes the compounds typically represented by 1-(4-pyridyl)piperidine-4-yl group.

The compounds of claim 1 of WO 96/10022 are illustrated by the following formula:



wherein  $\text{M}_1$  is a group of formula  $\text{NR}^2\text{-L}^1\text{-T}^1\text{R}^3$ .

The characteristic chemical formula part is from the ring including G to  $\text{M}_1$  which is typically represented by 1-(4-pyridyl)piperidine-4-yl group. It is noted that the compounds of the present application includes the compounds typically represented by 1-(4-pyridyl)piperidine-4-yl group.

In the Examination of the application of serial number 09/601,660 (registered as the '595 patent), the patentee argued against the Examiner's judicially-created doctrine of obviousness-type double patenting rejection over co-pending application of serial number 09/424,892 (registered as the '134 patent) as follows:

Applicants (patentee) disagree that the cited application ('134 patent) covers the same subject matter as the present application ('595 patent), as set forth in the claims as amended. In the cited application ('134 patent), the carbonyl group is a substituent pendant from ring A, while in the present application ('595 patent), as set forth in claim 1 as amended, ring A has a carbonyl on ring A, and no carbonyl pending from ring A. Furthermore, the cited application has no carbonyl on ring A. Applicants (patentee) submit that these differences do render the claims patentably distinct. The Examiner agreed with the argument and allowed the application to be registered as '595 patent appending a note of "subject to any disclaimer, the term of this

patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days. (parentheses added).

Therefore, the patentee of the '595 patent described that in the '134 patent, the ring A does not have a carbonyl group. On the contrary the compounds represented by the formula (I') of claim 1 of the present application include the compounds having the carbonyl on piperazine ring Y which is corresponding to ring A of '134 patent.

### Summary

As described above the present application is distinct from the '134 patent as follows.

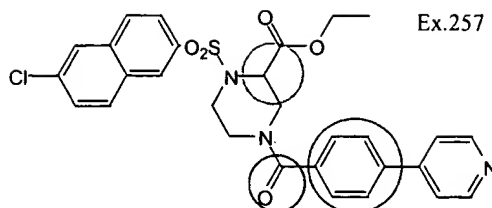
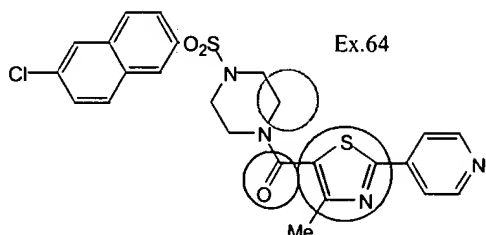
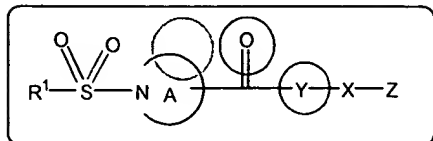
- (i) In the '134 patent neither claimed compounds nor working examples have the compounds typically represented by 1-(4-pyridyl)piperidine-4-yl group as Y-X-Z. On the contrary in the present application invented compounds are characterized the compounds typically represented by 1-(4-pyridyl)piperidine-4-yl group.
- (ii) In the claimed compounds of the '134 patent the ring Y is connected to the ring A through carbonyl group. On the contrary in the compounds of the present application the ring X is connected to the ring Y through alkylene group.

- (iii) Neither the compounds defined by claim 1 of the '134 patent have a carbonyl on ring A, nor the compounds in the working Examples of the '134 patent. On the other hand the typical compounds of the present application have a carbonyl on ring Y ( $R^6$  of ring Y) corresponding to ring A of the '134 patent.

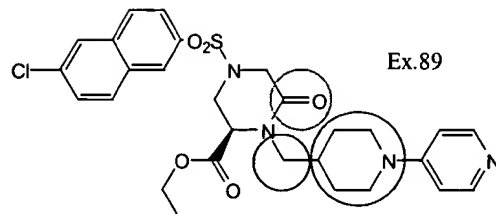
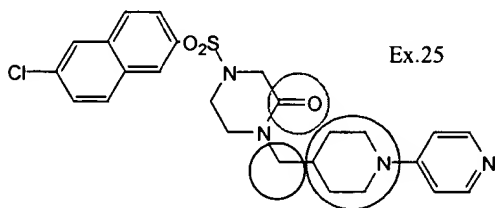
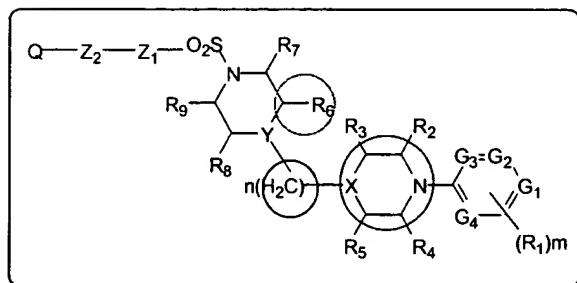
The comparison in chemical formulae of the compounds of the typical Examples between the '134 patent and present application are as follows. The circled groups are shown as characteristic parts of the '134 patent and the present application:



**US6,359,134(WO9854164)**

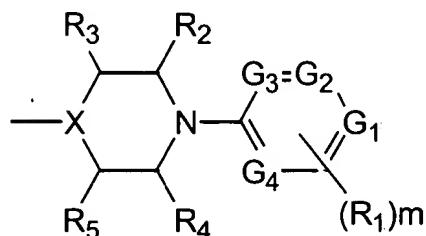


**US09/582,442(WO9933805/Mochida)**



Applicants have also attached a printout including the list of the data of the all compounds mentioned in the Examples of the '134 patent from the database of Caplus. The skilled artisan, upon review, can easily understand that the '134 patent as a whole is distinct from the present application. The compounds of the present application are characterized by the fact that the

following group, typically represented by 1-(4-pyridyl)piperidine-4-yl group is connected to the nitrogen atom in the piperazine ring having an oxo(carbonyl) group on the ring through alkylene group typically methylene group.



Accordingly, it is apparent that the present claims do not overlap with the claimed subject matter of the '134 patent. Also, the subject matter claimed in the '595 patent is distinct from the '134 patent. Accordingly, an interference proceeding is not necessary with the '134 patent.

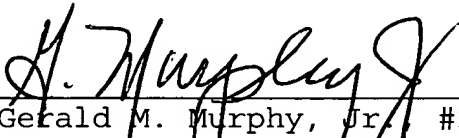
If the Examiner has any questions or comments, please contact the undersigned at the offices of Birch, Stewart, Kolasch & Birch, LLP.


Attached hereto is a marked-up version of the changes made to the application by this Amendment.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By   
Gerald M. Murphy, Jr. #28,977

  
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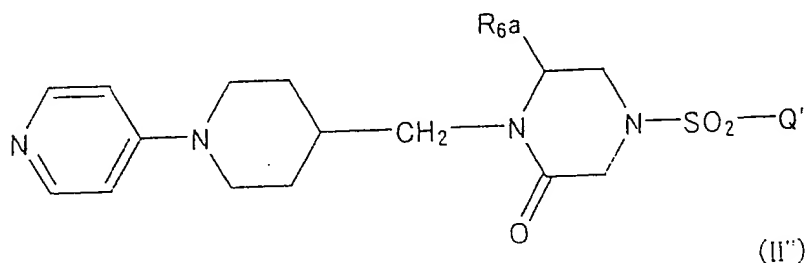
P.O. Box 747  
Falls Church, VA 22040-0747  
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Attachment: Version with Markings to Show Changes Made  
Printout from CAPLUS

VERSION WITH MARKINGS TO SHOW CHANGES MADEIN THE CLAIMS:

The claims have been amended as follows:

6. (Twice Amended) A compound of the formula (II''):



wherein

$R_{6a}$  is

1) a group selected from among a carboxyl group, a lower alkylcarbonyl group, a lower alkoxy carbonyl group, and a lower alkoxy carbonyl alkyl carbonyl group;

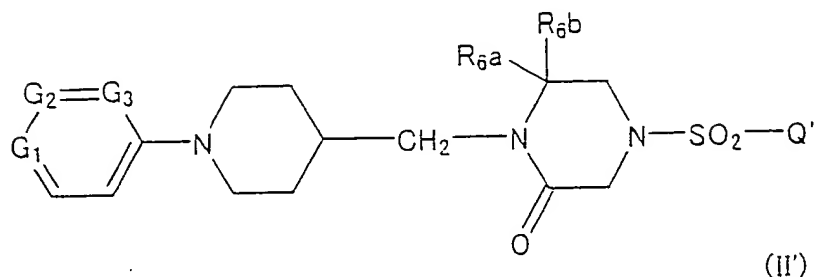
2) a group selected from among an optionally mono- or di-lower alkyl substituted carbamoyl group, a lower alkoxy carbamoyl group, a lower alkoxy carbonyl alkyl carbamoyl group, a pyrrolidin-1-yl carbonyl group, a morpholinocarbonyl group, a piperidin-1-yl carbonyl group which may be substituted by a methyl group or a hydroxyl group in 4-position, an N-phenyl carbamoyl group or a group selected from among the groups represented by the formulae

$-\text{CONH}(\text{CH}_2)_p\text{S}(0)_q\text{R}_{10}$  and  $-\text{CONH}(\text{CH}_2)_r\text{NR}_{11}\text{R}_{12}$  (wherein  $\text{R}_{10}$ ,  $\text{R}_{11}$ , and  $\text{R}_{12}$  are independently a hydrogen atom, a lower alkyl group, a phenyl group, or a lower alkylphenyl group;  $p$  is an integer of 0-4,  $q$  is an integer of 0-2, and  $r$  is an integer of 1-4), or

3) a lower alkyl group optionally substituted by  $\text{R}_{15}$ ;  $\text{R}_{15}$  is a carboxyl group, a lower alkoxy carbonyl group, a hydroxyl group, a lower alkoxy group, a lower alkanoyloxy group, an amino group, a mono- or di-substituted lower alkylamino group, a lower alkanoylamino group, a lower alkylsulfonylamino group, a cyclic amino group optionally substituted by a lower alkyl group or a hydroxyl group and being a pyrrolidinyl group, a piperidinyl group, a morpholino group, or a piperazinyl group, or an N-hydroxyimino group; and

$\text{Q}'$  [represents  $-\text{Z}_2-\text{Q}$ , wherein  $\text{Z}_2$  is a single bond, a lower alkylene group, a lower alkenylene group, or a lower alkynylene group and  $\text{Q}$  is an optionally substituted aryl group in the form of a monocyclic or fused hydrocarbon ring having 6-14 carbon atoms or an optionally substituted heteroaryl group in a monocyclic or fused cyclic form having 1-4 heteroatoms comprising an oxygen, a sulfur, or a nitrogen atom] is an aryl group or an aryl lower alkenylene group, whose aryl ring is in the form of a monocyclic or fused hydrocarbon ring having 6-14 carbon atoms and is optionally substituted by a group having any 1-4 halogen atoms,  
or a salt thereof.

19. (Amended) A compound represented by the following general formula (II') or a salt thereof:



(wherein  $G_1$ ,  $G_2$ , and  $G_3$  are independently CH or N, provided that one or two of them is N;

one of  $R_{6a}$  and  $R_{6b}$  is a hydrogen atom and the other is

1) a group selected from among a carboxyl group, a lower alkylcarbonyl group, a lower alkoxy carbonyl group, and a lower alkoxy carbonyl alkyl carbonyl group;

2) a group selected from among an optionally mono- or di-lower alkyl substituted carbamoyl group, a lower alkoxy carbamoyl group, a lower alkoxy carbonyl alkyl carbamoyl group, a pyrrolidin-1-yl carbonyl group, a morpholinocarbonyl group, a piperidin-1-yl carbonyl group which may be substituted by a methyl group or a hydroxyl group in 4-position, an N-phenyl carbamoyl group or a group selected from among the groups represented by the formulae  $-\text{CONH}(\text{CH}_2)_p\text{S}(0)_q\text{R}_{10}$  and  $-\text{CONH}(\text{CH}_2)_r\text{NR}_{11}\text{R}_{12}$  (wherein  $R_{10}$ ,  $R_{11}$ , and  $R_{12}$  are independently a hydrogen atom, a lower alkyl group, a phenyl group,

or a lower alkylphenyl group; p is an integer of 0-4, q is an integer of 0-2, and r is an integer of 1-4), or

3) a lower alkyl group optionally substituted by  $R_{15}$ ;  $R_{15}$  is a carboxyl group, a lower alkoxy carbonyl group, a hydroxyl group, a lower alkoxy group, a lower alkanoyloxy group, an amino group, a mono- or di-substituted lower alkylamino group, a lower alkanoylamino group, a lower alkylsulfonylamino group, a cyclic amino group optionally substituted by a lower alkyl group or a hydroxyl group and being a pyrrolidinyl group, a piperidinyl group, a morpholino group, or a piperazinyl group, or an N-hydroxyimino group;

or  $R_{6a}$  and  $R_{6b}$  are both the same lower alkyl group;

$Q'$  [represents  $-Z_2-Q$ , wherein  $Z_2$  is a single bond, a lower alkylene group, a lower alkenylene group, or a lower alkynylene group and  $Q$  is an optionally substituted aryl group in the form of a monocyclic or fused hydrocarbon ring having 6-14 carbon atoms or an optionally substituted heteroaryl group in a monocyclic or fused cyclic form having 1-4 heteroatoms comprising an oxygen, a sulfur, or a nitrogen atom)] is an aryl group or an aryl lower alkenylene group, whose aryl ring is in the form of a monocyclic or fused hydrocarbon ring having 6-14 carbon atoms and is optionally substituted by a group having any 1-4 halogen atoms.